



Patent Application  
Docket No. USF-167XC1  
Serial No. 10/815,388

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Allison M. Ford  
Art Unit : 1651  
Applicants : Pablo Caviedes, Raul Caviedes, Thomas B. Freeman, Juan A. Asenjo,  
Barbara A. Andrews, Dario Sepúlveda, Christian Arriagada, Julio Salazar  
Rivera  
Serial No. : 10/815,388  
Filed : March 31, 2004  
For : Materials and Methods for Regulating Process Formation in Cell Culture

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION OF PABLO CAVIEDES, M.D., UNDER 37 C.F.R. §1.132

Sir:

I, Pablo Caviedes, M.D., hereby declare:

THAT, I am a professor in the Program of Molecular and Clinical Pharmacology, ICBM,  
Faculty of Medicine at the University of Chile;

THAT, I am a co-inventor of the technology described and claimed in patent application  
Serial No. 10/815,388 (hereinafter the '388 application);

THAT, I am a co-author on the following presentation: Andrews *et al.*, entitled "Factors for  
the Optimization of the Culture of Neuronal Cell Lines for the Development of Cell Transplant  
Material" (Poster presentation from Cell Culture and Engineering Conference in Snowmass, CO,  
2002);

THAT, I have read and understood the specification and claims of the '388 application, the  
Office Action dated September 27, 2005, and the references cited in the Office Action;

AND, being thus duly qualified, do further declare:

1. Claims 18-26 and 28-29 in the '388 application have been rejected under 35 U.S.C. §102(a) in the Office Action dated September 27, 2005 on the grounds that the claimed invention is anticipated by the above-identified Andrews *et al.* presentation. The inventorship of the claimed invention and the authorship of the Andrews *et al.* presentation differ in that although Thomas B. Freeman, Christian Arriagada, and Julio Salazar Rivera are inventors on the subject application, they are not co-authors of the Andrews *et al.* presentation. Furthermore, the inventorship of the claimed invention and the authorship of the Andrews *et al.* publication differ in that although P. Venegas (Paola Venegas) is a co-author of the Andrews *et al.* presentation, she is not named as an inventor on the subject application. Thus, R. Caviedes (Raul Caviedes), J.A. Asenjo (Juan A. Asenjo), B.A. Andrews (Barbara A. Andrews), D. Sepulveda (Dario Sepulveda), and myself, are co-authors of the Andrews *et al.* presentation and are inventors on the subject application.

2. As the Examiner may be aware, it is not uncommon for persons other than those involved in the conception of an invention to be listed as co-authors on a scientific publication resulting from the research related to the invention. Furthermore, it is not uncommon for persons involved in the conception of an invention to be excluded as co-authors on related scientific publications with which they were not directly involved. These are the circumstances surrounding the Andrews *et al.* presentation and the subject matter claimed in the '388 application.

3. P. Venegas did not contribute to the conception of the claimed invention. Ms. Venegas was an undergraduate student assigned to my laboratory for practice rotations, and was included as a co-author on the Andrews *et al.* presentation because she assisted me by occasionally carrying out initial culture duties (*e.g.*, cryopreservation, cell feeding, preparation of reagents) under my direct supervision. Therefore, Ms. Venegas was included as a co-author of the Andrews *et al.* presentation, but is not an inventor of the claimed invention.

4. Dr. Thomas B. Freeman contributed to the conception of the claimed invention. The information contained in the Andrews *et al.* presentation represents preliminary work in which the objective was to determine conditions in which cells could be more efficiently cultured in order to

obtain large masses of cells in reduced spaces or volumes, with contemplated applications including the extraction of cell products (e.g., neurotrophic factors) and cell transplantation. Dr. Freeman determined the size and geometry of neuronal cell aggregates conducive to cell transplantation, and the culture time and conditions necessary to obtain them. Dr. Freeman was not included as a co-author of the Andrews *et al.* presentation because he participated in the research carried out subsequent to the experiments described in the presentation.

5. Christian Arriagada and Julio Salazar Rivera contributed to the conception of the claimed invention. Mr. Arriagada and Mr. Salazar Rivera designed and carried out morphological experiments to determine when cells in the center of the cell aggregates started to become necrotic (degenerate). In addition, Mr. Salazar Rivera carried out initial transplant studies in Parkinsonian rats. Mr. Arriagada and Mr. Salazar Rivera were not included as co-authors of the Andrews *et al.* presentation because they participated in the research carried out after the experiments described in the Andrews *et al.* presentation.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

Further declarant sayeth naught.

Signed:

  
Pablo Caviedes, M.D.

Date:

January 26<sup>th</sup>, 2006